

## AMENDMENTS

### Listing of Claims

The following listing of claims replaces all previous listings or versions thereof:

1. (Original) A method for evaluating the risk of irinotecan toxicity in a patient comprising determining the presence of a polymorphism in one or both *UGT1A1* genes of the patient, wherein the polymorphism is in linkage disequilibrium with a *UGT1A1* TA repeat.
2. (Original) The method of claim 1, further comprising amplifying from a nucleic acid sample all or part of 5' flanking region of one or both *UGT1A1* genes to obtain amplification products and analyzing the amplification products for the presence or absence of a polymorphism.
3. (Original) The method of claim 1, wherein the polymorphism is at nucleotide position -3440, -3401, -3279, -3177, -3175, or -3156 from the *UGT1A1* gene transcriptional start site.
4. (Original) The method of claim 1, wherein the number of TA repeats is 5, 6, 7, or 8 TA repeats.
5. (Currently amended) The method of claim 1, wherein the polymorphism is a -3279G>T [-3440C>A] polymorphism.
6. (Currently amended) The method of claim 5 [1], further comprising determining the presence of a polymorphism in one or both *UGT1A1* genes of the patient, wherein the polymorphism is a -3401T>C polymorphism.
7. (Currently amended) The method of claim 5 [1], further comprising determining the presence of a polymorphism in one or both *UGT1A1* genes of the patient, wherein the polymorphism is a -3440C>A [-3279G>T] polymorphism.

8. (Currently amended) The method of claim 5 [1], further comprising determining the presence of a polymorphism in one or both *UGT1A1* genes of the patient, wherein the polymorphism is a -3177C>G polymorphism.
9. (Currently amended) The method of claim 5 [1], further comprising determining the presence of a polymorphism in one or both *UGT1A1* genes of the patient, wherein the polymorphism is a -3175A>G polymorphism.
10. (Currently amended) The method of claim 5 [1], further comprising determining the presence of a polymorphism in one or both *UGT1A1* genes of the patient, wherein the polymorphism is a -3156G>A polymorphism.
11. (Currently amended) The method of claim 10 [1], wherein determining the presence of a polymorphism in one or both *UGT1A1* genes of the patient comprises determining the nucleotide sequence at position -3156 in one or both genes.
12. (Original) The method of claim 11, further comprising classifying the *UGT1A1* activity level in the patient, whereby identification of a guanine residue indicates the patient does not have a low level of activity.
13. (Original) The method of claim 11, further comprising determining the nucleotide sequence at position -3156 of a second *UGT1A1* gene in the patient.
14. (Original) The method of claim 11, further comprising administering irinotecan to the patient if a guanine nucleotide is found at position -3516.
15. (Original) The method of claim 1, further comprising analyzing a glucuronidation rate associated with the polymorphism.
16. (Original) The method of claim 1, further comprising optimizing a dose of irinotecan for administration to the patient.

17. (Original) The method according to claim 1, wherein determining the presence of a polymorphism of a UGT1A1 gene or genes is performed by a hybridization assay.
18. (Original) The method according to claim 1, wherein determining the presence of a polymorphism of a UGT1A1 gene or genes is performed by a sequencing or microsequencing assay.
19. (Original) The method according to claim 1, wherein determining the presence of a polymorphism of a UGT1A1 gene or genes is performed by an allele-specific amplification assay.
20. (Original) The method of claim 1, further comprising administering to the patient irinotecan.
21. (Original) The method of claim 20, further comprising administering to the patient a second agent to reduce excretion of an active irinotecan species through the bile.
22. (Currently amended) A method for evaluating the risk of irinotecan toxicity in a patient comprising:  
determining the nucleotide sequence at position -3279G>T and -3156 in one *UGT1A1* gene of the patient.
23. (Original) The method of claim 22, further comprising classifying the UGT1A1 activity level in the patient, whereby identification of a guanine residue indicates the patient does not have a low level of activity.
24. (Original) The method of claim 22, further comprising determining the nucleotide sequence at position -3156 of a second *UGT1A1* gene in the patient.
25. (Original) The method of claim 22, further comprising administering irinotecan to the patient if a guanine nucleotide is found at position -3516.

26. – 33. (Canceled)